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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,024	03/20/2001	Jonathan Henry Ellis	1430-263	2645

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Nixon & Vanderhye
1100 North Glebe Road 8th Floor
Arlington, VA 22201-4714

EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,024

Applicant(s)

ELLIS, JONATHAN HENRY

Examiner

Larry R. Helms

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/16/01, 8/5/04</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1642

DETAILED ACTION

Election/Restrictions

1. The election of newly added claims 14-20 with traverse in the paper filed 8/5/04 is acknowledged. Due to the cancellation of claims 1-13 and the addition of claims 14-20 drawn to a single invention, the restriction is moot.
2. Claims 14-20 are pending and under examination.

Specification

3. The disclosure is objected to because of the following informalities:
 - a. The disclosure on page 22, line 1, 2, 5, 7, 10, as well as other places, contains the term "□" which needs to be replaced with micro.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 14-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of assaying binding, identifying a compound, assaying for inhibition between SEQ ID NO:5 or amino acids comprising

Art Unit: 1642

those encoded by nucleotides 151-459 of SEQ ID NO:4 and a human CD28 molecule phosphorylated at tyrosine 173, does not reasonably provide enablement for a method of assaying binding, identifying a compound for treatment of a disorder involving CD28 expressing cells, assaying for inhibition between SEQ ID NO:5 or amino acids comprising those encoded by nucleotides 151-459 of SEQ ID NO:4 and a human CD28 molecule not phosphorylated at tyrosine 173, wherein the disorder is any disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The claims are broadly drawn to assaying binding between SEQ ID NO:5 or residues encoded by 151-459 of SEQ ID NO:4 and a human CD28 protein (and a compound) wherein the CD28 protein is not phosphorylated at residue 173. Also the claims broadly encompass identifying a compound that inhibits the binding between CD28 and SEQ ID NO:5 or residues encoded by 151-459 of SEQ ID NO:4 wherein the compound is used for the treatment of any disorder involving CD28 expressing cells

Art Unit: 1642

wherein it is also broadly encompassed by a disorder which is not related to CD28's function.

The specification teaches that SH2 domains require phosphotyrosine for their binding sites and phosphorylated CD28 is needed for protein-protein interactions with SH2 domains (see page 9 and 12) and GRIP binds to CD28 as demonstrated in Example 8 wherein the control peptide which was not phosphorylated did not bind but the phosphorylated peptide did bind (see page 21) and GRIP SH2 domain interact with CD28 centered around phosphorylated tyrosine 173 (see page 22-23). The specification does not enable any compound that inhibits the binding between CD28 and SEQ ID NO:5 or residues 151-459 of SEQ ID NO:4 for the treatment of any disorder.

The claims are not commensurate in scope with the enablement provided in the specification. The specification (as described above) as well as the prior art as evidenced by Ellis et al (The Journal of Immunology 2000, 164:5805-5814) teach that GRID (which is GRIP in the specification) must have tyrosine phosphorylated in CD28 in order for GRID to bind (see figure 6). Thus, one would not expect binding to CD28 and GRIP or GRID to occur as broadly claimed with a non-phosphorylated CD28 molecule.

Claims 17, 19-20 are broadly drawn to identifying a compound that inhibits CD28 and GRIP interaction for the treatment of any disorder, or those specifically recited in claims 19-20, wherein the claims broadly encompass the disorder only involves CD28 expressing cells. The claims broadly encompass a disorder that does not have to have or identified as having CD28/GRIP interactions that cause the disorder. The

Art Unit: 1642

specification does not teach that disruption of the CD28 and GRIP interactions lead to any treatment of any disorder. The specification does not teach any compound that inhibits the interaction can be used to treat any disorder. As evidenced from Okkenhaug et al (The J. of Biol. Chem 273:21194-202, 1998) and Kim et al (The J. of Biol. Chem 273:296-301, 1998) GRB2 (of which is highly homologous to GRIP) forms a complex with CD28 but the art does not identify any compounds or disruption of this interaction would lead to treatment of any disorder affecting CD28. Thus, it is unpredictable that a compound that inhibits the binding of CD28 and GRIP would be used to treat any CD28 disorder or a disorder resulting from CD28 and GRIP interaction.

Therefore, in view of the lack of guidance in the specification and in view of the discussion above one of skill in the art would be required to perform undue experimentation in order to practice the claimed invention.

Conclusion

6. No claim is allowed. The closest prior art that reads on the claims is Okkenhaug et al (The J. of Biol. Chem 273:21194-202, 1998) and Burgess et al (EMBL DATABASE accession number 043726, 6/98, PTO 892, 5/5/04). Burgess et al teach a polypeptide that is identical to the amino acids encoded by nucleic acid residues 151-459 of SEQ ID NO:4, but does not teach a method of assaying. Okkenhaug et al teach GRB2 forms a complex with CD28 and the association of CD28 and GRB2 can occur in the absence of tyrosine phosphorylation which is known to occur with the SH2 domain of GRB2 and

Art Unit: 1642


CD28. Thus, one would not have a reasonable expectation of success to combine the references because the SH2 domain, which is what resides 151-459 of SEQ ID NO:4 is, is not taught to be important in the GRB2 protein in binding to CD28, thus, one would not substitute the molecule of Burgess et al with that of GRB2.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew, can be reached at (571) 272-0787.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is 703-872-9306.

Larry R. Helms

571-272-0832



LARRY R. HELMS, PH.D
PRIMARY EXAMINER